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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,843	09/06/2005	Takashi Horiguchi	Q101074	9679

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/547,843	HORIGUCHI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/28/8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 4-7 and 17 are pending and under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on October 28, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 4-7 and 17 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 5 of Paper mailed on May 11, 2007, in section 5 of Paper mailed on October 10, 2007 and in section 6 of Paper mailed on May 07, 2008.

At pp. 2-3 of the Response, Applicant submits that, "[t]he biological activity of C1 protein of SEQ ID NO: 1 is taught in the Examples of the present application. Specifically, the Examples teach i) that expression of C 1 is enhanced in rat primary nerve cells that have been subjected to endoplasmic reticulum stress (Example 1), ii) that the expression of C 1 is also enhanced in rat primary nerve cells that have been stimulated with J3 amyloid (Example 2), iii)

that C1 promotes cell death in SK-N-AS cells (human neuroblastoma) (Example 4), and iv) that C 1 inhibits secretion of A1340 and A1342 in IMR-32 cells (human neuroblastoma) (Example 5)". Applicant further states that, "the state of art at the time of invention has established such connection between Alzheimer's disease and Aβ" and refers to article of Seubert et al.. Finally Applicant argues that the experimental results of decreased secretion of Aβ from cell transfected with C1 " proves the specific, substantial and credible utility [of the claimed protein] to diagnose and treat Alzheimer's disease. Indeed, Siemers et al. […], and Fleisher et al. […] report clinical trails for the compound LY450139 having the Aβ secretion inhibitory activity to evaluate its safety, tolerability and Aβ response as a therapeutic agent for Alzheimer's disease", p. 4 of the Response. Applicant's arguments have been given careful consideration but are not found to be persuasive for the following reasons.

As fully explained in the previous communications of record, the instant claimed protein of SEQ ID NO: 1 and its encoded DNA do not meet the requirements of 35 USC 101 as being useful because the instant specification fails to disclose even one specific and substantial credible utility for the claimed molecules. According to legal standard, a specification can meet the utility and enablement requirement for a new polypeptide or polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new molecules(an "evidence"), or a well-established utility for the claimed molecules would be *prima facie* obvious to the skilled artisan ("sound scientific reasoning"). Thus, the law requires that the patent application describes the utility of the claimed invention based on evidence or obviousness to one skilled in the art. The Examiner maintains that in the instant case, the asserted utility of the polypeptide of SEQ ID NO: 1 "to diagnose and treat Alzheimer's disease" is not supported by

any factual evidence or sound scientific reasoning at the time of filing. Specifically, there is no disclosure that the instant polypeptides or polynucleotides can be used as a marker for AD, or that the polypeptide of SEQ ID NO: 1 can be used for therapeutic purposes to treat AD. The result of experiments performed on cells with artificially altered genotype do not make it immediately obvious for one of skilled in the art that the instant C1 protein has a specific role in etiology of AD. Thus, since the evidence of record is inadequate to support the asserted utility of the C1 protein, the instant invention clearly does not meet the requirement of 35 USC 101. Applicant's argument that there are compounds, like LY450139, that decrease Aβ secretion and therefore have potential therapeutic significance in AD treatment, is not disputed. However, in the instant case, the evidence of record does not provide for C1 to be one of those compounds because there is no record of suppression of Aβ secretion upon administration of C1. One skilled in the art readily appreciates that the genetically altered cells are reasonably expected to express different types/amounts of proteins as compare to wild type cells. There is no explanation given in the specification or presented by Applicant that would allow a conclusion that C1 overexpression is directly associated with the biological significance of C1 protein in Aβ secretion process.

For reasons of record in the previous office actions of record and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

> pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4-7 and 17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 17 stands rejected under 35 U.S.C. 112, second paragraph, for reasons of record in section 10 of Paper mailed on May 07, 2008. The Examiner maintains that since the activity of the C1 protein is not known, see reasoning in section 5 of the instant office action, one skilled in the art would now know as what material limitations define the claimed subject matter, a kit for screening a compound that promotes or inhibits the activity of the protein of SEQ ID NO: 1, and the rejection is maintained.

Conclusion

10. No claim is allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
December 05, 2008

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649